EXHIBIT DX1

TO DECLARATION OF
DEBORAH E. LEWIS IN SUPPORT
OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTION
TO EXCLUDE TESTIMONY OF
ALEXANDER A. HANNENBERG, M.D.

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ANESTHESIOLOGY

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May 30, 2017

Deborah Lewis, Esq. Blackwell Burke 431 South 7th Street, Suite 2500 Minneapolis, MN 55415

Re: Bair Hugger Forced Air Warming Product Liability

Dear Ms. Lewis.

Per your request, I have reviewed materials relating to the Bair Hugger Forced Air Warming Product Liability lawsuit and provide the following opinions.

Professional background and experience

I completed my residency training in anesthesiology in 1984 and practiced continuously until 2017, practicing for 26 years at Newton-Wellesley Hospital in Newton, MA. I have been continuously licensed in Massachusetts since 1980. I have been certified by the American Board of Anesthesiology since 1984 and currently hold the position of Clinical Professor of Anesthesiology at Tufts University School of Medicine. I am a faculty member in Safe Surgery program of Ariadne Labs, a health systems innovation center at the Harvard T.H. Chan School of Public Health and Brigham & Women's Hospital. I served as an examiner for the American Board of Anesthesiology from 2000-2015. I have held numerous positions in the American Society of Anesthesiologists including its presidency in 2010 and, most recently, as its Chief Quality Officer. During the years prior, I had responsibility for the Society's work in the area of professional standards, performance measurement, patient safety and other related areas. Consequently, I participated as chair of the American Medical Association's Physician Consortium for Performance Improvement workgroup developing performance measures in anesthesiology and critical care in 2007 and again when the group reconvened in 2012. Among the measures developed was one addressing perioperative temperature management that was subsequently adopted by Medicare's Physician Quality Reporting System and endorsed by the National Quality Forum. This measure was chosen because of the recognized practice gap in effective intraoperative temperature management and the resulting preventable morbidity. My experience and education is more fully set forth in my Curriculum Vitae, attached hereto as Exhibit A.

Over these 30+ years, my practice consistently included administering anesthesia for major orthopedic surgery. I have provided anesthesia for more than 400 total joint replacement operations. For the more than twenty years since we have had access to Bair Hugger forced air warming technology, I have applied it in virtually every hip or knee replacement and I understand it to be widely chosen by anesthesiologists nationwide. The use of forced air warming has provided patient comfort and reduced postoperative shivering, a side effect that is very unpleasant for patients in addition to reducing the risk of cardiovascular and bleeding complications. I have found forced air warming to be safe, easy to use, and effective at maintaining patients' normal temperatures. In addition, it has been part of my strategy to reduce the likelihood of surgical site infection in my practice at Newton-Wellesley Hospital which exclusively uses Bair Huggers for intraoperative patient warming. In recent years, the rate of infection in our institution has been 0.6%, approximately half the prevailing national infection rate.

Materials reviewed.

In preparing my opinions, I have considered the literature and discovery material pertinent to this case listed in Exhibit B.

I may use all or parts of these materials, or summaries and depictions thereof, as exhibits or demonstrative aids to summarize or support my opinions.

Opinions

The below opinions are given to a reasonable degree of medical and scientific certainty. They are based upon my education, training, experience, and knowledge of the literature, as well as the above list of materials reviewed.

Optimal patient care in arthroplasty surgery includes forced air warming.

Hypothermia poses many risks to surgical patients, including and especially an increased risk of surgical site infection in arthroplasty patients. The most effective method of reducing these risks is through the use of forced air warming. This practice is endorsed by multiple independent and highly respected groups worldwide including: ECRI Institute¹, AMA Physician Consortium for Performance Improvement, US Centers for Medicare & Medicaid Services², American Society of Perianesthesia Nurses³, the UK National Institute for Clinical Excellence (NICE)⁴ as well as the leading US textbook of anesthesiology, Miller's Anesthesia⁵. These sources recommend not only patient warming, but specifically recommend the use of forced air warming to maintain normothermia. The landmark study⁶ demonstrating that prevention of hypothermia reduced the risk of surgical site infection notably used forced air patient warming to achieve normothermia and the associated reduction in wound infection rate. While Kurz does not directly address hip and knee arthroplasty, the results should guide management of arthroplasty cases because the known physiologic effect of hypothermia impairing peripheral

circulation gives the findings face validity. Host defenses against microbial infection depend on delivery of oxygen and leukocytes to the surgical wound through adequate microcirculation. In this sense, hip and knee replacements are much more similar to colectomy than they are different.

In my clinical practice, the decision to universally employ forced air warming in my arthroplasty patients is guided by the above sources and other relevant literature, awareness of peer group practice, the evidence of efficacy from the literature^{7,8,9,10} and from my personal clinical experience. The Bair Hugger is a safe and efficacious device.

Clinical tactics to mitigate the risk of surgical infection

Controlling the risk of infection is a multidisciplinary collaboration involving all operating room personnel. The anesthesiologist influences a number of factors known to impact the frequency of surgical infections. In addition to maintaining normothermia, the anesthesiologist must make every effort to avoid hyperglycemia and to administer appropriate antibiotic prophylaxis in a timely fashion. The team's adherence to sterile operating room technique, surgical tissue handling, duration, cleanliness and sterility of surgical instruments and implants are among the many factors underlying the extent of wound contamination which to a greater or lesser degree is inevitable, occurring as frequently as 89% in cardiac surgical procedures¹¹ and 30% in clean orthopedic surgery¹². The counterbalancing factors influencing the development of a clinically significant wound infection relate to patient defense factors. Major considerations in determining the efficacy of these factors include the integrity of the circulation delivering oxygen and white blood cells to the tissues in the surgical wound. Many patient co-existing conditions are known to impair these defenses, as are acute perturbations in patient physiology occurring during surgery and anesthesia, notably including hypothermia. Minimizing these disturbances is the goal of intraoperative patient management.

Theoretical concerns about forced air warming disrupting laminar flow are irrelevant and based on invalid experimental models.

The benefits of operating room laminar flow ventilating systems remain difficult to demonstrate and these costly systems are now rarely installed in new operating rooms. The best controlled and most influential study on this question, including more than 99,000 operations, concluded in 2008 that "OR ventilation with laminar airflow showed no benefit and was even associated with a significantly higher risk for severe SSI after hip prosthesis.¹³" The American Society of Anesthesiologists OR Design Manual states: "Careful mathematical analyses of airflow suggest laminar airflow is not necessary when the previously noted recommendations are met. Clinical studies are confirmatory.¹⁴" Thus, a conclusion that interference with an air handling technology that does not clearly reduce infection risk cannot logically imply that this putative interference, if it were demonstrated in a valid experimental model, results in an elevated infection risk.

Despite weak evidence for its benefit, lower extremity arthroplasty surgery may be performed in a laminar air flow environment. Proper use of laminar flow systems requires that only essential personnel and equipment be located in the laminar flow area, often indicated by floor markings or plexiglass overhead curtains. For this reason, anesthesia equipment, including the Bair Hugger, anesthesia machine and monitors and anesthesia personnel are located outside the laminar flow area. It is not feasible to locate the large, unsterile surgical lights outside of the laminar flow area and these inevitably sit directly between the origin of the laminar air flow and the surgical incision. In addition, the patient's head and often arms are situated outside the laminar flow area, particularly during lower extremity surgery, because anesthesia providers will have frequent need to access these areas. Since the Bair Hugger upper body warming blanket is tightly secured to the patient's skin at its distal end (usually mid-thorax) with an adhesive strip, is wrapped around the patient's arms, and is further covered by multiple layers of adhesive sterile surgical drapes excluding the blanket from the vicinity of the surgical wound, the main area of egress of hot air is around the head and neck where the blanket is loosely applied. This results in any hot air escaping both far from the surgical wound and outside the laminar flow environment. Thus, alleged effects of the Bair Hugger on laminar flow in the experimental environment are largely irrelevant to actual clinical practice. The opinions of plaintiffs' experts Drs. Stonnington and Jarvis largely rely on this entirely unproven relationship. In addition, these experts also attribute the alleged risk of the Bair Hugger device to the bacterial content of the internal and external surfaces of the device and the output of the Bair Hugger hose. Virtually all of the devices and surfaces in an operating room, except those in the surgical field, are non-sterile and the Bair Hugger hose is never delivering air directly to the patient without a blanket. Based on a frequently cited study, the air emitted from the Bair Hugger blanket does not produce bacterial growth when cultured. ¹⁵ This finding – negative cultures of Bair Hugger blanket air flow - also discredits allegations of the inadequacy of air filtration in the Bair Hugger. For these reasons, I disagree with the opinions of Drs. Stonnington and Jarvis on the Bair Hugger causing a risk of surgical site infection because the foundation of those opinions is defective.

The sole study cited by plaintiffs to relate clinical infection to Bair Hugger use relies on an experimental model used to demonstrate disrupted laminar flow that is inherently flawed. Body heat emanating from surgical staff, the effect of the constant movement of 3-4 scrubbed individuals, movement of instruments in the laminar flow environment all can be expected to have an influence on the flow of air around the patient's surgical wound; these accurately describe the actual environment in which total joint replacement procedures are performed. So, a model such as used by McGovern et al¹⁶ to demonstrate this phenomenon that has one individual at the surgical site "motionless" is highly unrealistic, excludes important influences on air movement and cannot form the basis for any conclusion about either laminar flow or surgical infection risk. McGovern's conclusions are also invalid because of other, highly relevant contemporaneous changes in infection prevention practices during the study period. Indeed, McGovern concedes that his

"study does not establish a causal basis" for an alleged association between the Bair Hugger and surgical site infections.

Impartial and authoritative review of warming technology supports the safety of forced air warming.

Clinicians rely on impartial and expert review of the available science to guide clinical decision making. After undertaking a comprehensive and exhaustive review of the available evidence specifically on the question of whether hot air warming devices pose an infection risk, the ECRI concluded in 2013 that they did not.¹ ECRI is a formally designated Evidence-Based Practice Center of the U.S. Agency for Healthcare Research and Quality, established more than forty years ago. More than 5,000 public and private institutions rely on ECRI for evidence reports and assessments of health care technology. Similarly, the National Institutes of Health concludes that "forced-air warming technology does not increase the risk of surgical wound infection.^{17"} In 2013, the International Orthopedic Consensus Meeting on Periprosthetic Joint Infection also concluded – by a nearly unanimous vote - that there was no evidence linking forced air warming with an increased incidence of surgical infections in joint replacement surgery. ¹⁸ In the same year, the Association of PeriOperative Registered Nurses (AORN) stated in its evidence-based practice recommendations "Forced air warming is safe and the most widely used skin surface warming method...Forced air warming does not increase the risk of wound contamination.19"

Notably, during the nearly ten years of their campaign focused on discrediting forced air warming, organizations linked to Hot Dog warming systems, such as heatrises.blogspot, Orthopedic Infection Advisory and Stop Surgical Infections.org have not produced or disseminated <u>a single credible study</u> associating forced air warming with an increased frequency of clinical wound infection in any setting, relying instead on broadcasting studies on speculative, surrogate measures relating to particles, air flow and parameters other than clinically relevant events.

Cardiovascular heater-cooler device issues are not relevant to forced air warming technology.

Plaintiffs' experts refer to a 2016 FDA Safety Communication²⁰ addressing a risk of nontuberculous mycobacterial infection in cardiac surgery patients reportedly tracked to a water heater-cooler device used in conjunction with cardiopulmonary bypass circuits. The incidents involve the product of a single manufacturer whose production line reportedly contaminated the heater-cooler pumps before they left the factory. The vector of patient infection was *water vapor* carrying the bacteria and spread in the operating room by the device's fan. Thus, it was not the air from the device but the water vapor it carried that led to the infections. The FDA describes the mechanism of contamination by saying: "Although the water in the circuits does not come into direct contact with the patient, there is the potential for *contaminated water to enter other parts of the device and aerosolize*, transmitting

bacteria through the air and through the device's exhaust vent into the environment and to the patient."

In addition, this was a time-limited problem and the FDA states it is unaware of any similar infections associated with devices manufactured after 2014. Forced air warming devices do not contain or circulate any water and thus are not susceptible to the problem described in this FDA Safety Communication. There is no history of device contamination during manufacture of the Bair Hugger as was the case with the cardiovascular heater-coolers.

The Bair Hugger's labeling and design were reasonable

From the perspective of an anesthesiologist, the warnings and labeling for the Bair Hugger and its blankets are clear and easily understood, and include instructions regarding the setup of the device and blanket. For the reasons discussed above, the labeling appropriately did not include warnings regarding a risk of infection being caused by the use of the Bair Hugger, for which there is no credible evidence. The diligence of the manufacturer in reliably and aggressively warning clinicians of legitimate device hazards is amply demonstrated by the highly visible and effective campaign to warn against improper use of the device without a warming blanket, known as "hosing²¹" in which the Bair Hugger hose is improperly applied directly to the patient possibly resulting in thermal injury.

Conclusions

- The evidence that maintaining normothermia improves outcomes in surgical patients is firmly established, and this improvement includes a reduction in the risk of surgical site infection.
- Forced air warming devices, in particular the Bair Hugger, have a compelling body of evidence to support their safety and efficacy ^{7,8,9,10}. Additionally, the Bair Hugger labeling is reasonable and did not need to include a warning of an alleged risk of surgical site infections.
- For these reasons, the practice of using forced air warming in surgical patient care is endorsed by numerous impartial and objective groups that have scrutinized the available evidence. These endorsements establish a standard of care in anesthesia and surgical practice.
- According to the literature and my personal experience, the Bair Hugger does not cause surgical site infections. I am not aware of a single credible scientific study causally linking the use of the Bair Hugger to an increased risk of surgical site infections.

• The studies that address disruptions in laminar flow or increased airborne particle counts do not demonstrate an increased frequency of clinical infection. The only study¹⁶ that is cited to demonstrate this risk is severely limited and its own authors, with a disclosed financial interest in the subject, disavow drawing such a conclusion from their work: "This study does not establish a causal basis for this association. Although the demographics were similar between the patient groups in terms of risk factors for infection, the data are observational and may be confounded by other infection control measures instituted by the hospital...In addition, we were unable to consider all factors that have been associated with SSI..." Thus, there is no study demonstrating a causal relationship between forced air warming technology and surgical site infections.

This report is not meant to be an exhaustive recitation of all of my opinions. I reserve the right to amend and supplement the opinions expressed in this report. I also reserve the right to respond to and rebut all information provided in discovery, which I understand is ongoing, specifically including any opinions offered by Plaintiffs' experts at their depositions or at trial.

Fees

My fees for medicolegal consulting are \$500 per hour for document review and reports; for appearances at deposition or trial locally, \$2000 for the first hour and \$200 each subsequent hour; for appearances at deposition or trial more than 100 miles from Wellesley MA, \$3000 for the first hour and \$200 each subsequent hour.

Prior Testimony

I have testified at a deposition on March 10, 2014 in Cohen vs Saint Francis Hospital (Superior Court of Hartford CT) and on no other occasion in the past four years.

Alexander A. Hannenberg, M.D.

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https://www.nice.org.uk/guidance/cg65/chapter/Recommendations#intraoperative-phase. Accessed May 19, 2017

¹ ECRI Institute. Forced-air warming and surgical site infections. *Health Devices*. 2013; 122-125

² Centers for Medicare & Medicaid Services, 2016 Physician Quality Reporting System Measure Specification. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2016_PQRS_IndivMeasures_Guide_11_17_2015.pdf. Accessed May 19. 2017

 $^{^3}$ Hooper VD et al. ASPAN's Evidence-Based Clinical Practice Guideline for the Promotion of Perioperative Normothermia: Second Edition. J PeriAnesthesia Nursing 2010 (25) 346-364

⁴ Hypothermia: prevention and management in adults having surgery. National Institute for Health and Care Excellence CG65

⁵ Miller RD, ed. Miller's Anesthesia, 7th edn. Churchill Livingstone 2010

⁶ Kurz A., et al. Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization. *N Engl J Med.* 1996;334:1209-15.

⁷ Hynson JM, Sessler DI. Intraoperative warming therapies: a comparison of three devices. *J Clin Anesth.* 1992;4:194-199

⁸ Giesbrecht GG, et al. Comparison of forced-air patient warming systems for perioperative use. *Anesthesiology*. 1994; 80:671-679.

⁹ Berti M, et al. Active warming, not passive heat retention, maintains normothermia during combined epidural-general anesthesia for hip and knee arthroplasty. *J Clin Anesth.* 1997;9:482-486.

 $^{^{10}}$ Kurz A, et al. Forced-air warming maintains intraoperative normothermia better than circulating-water mattresses. Anesth Analg. 1993;77:89-95

 $^{^{11}}$ Kühme, T., Isaksson, B, Dahlin L.-G. (2007), Wound contamination in cardiac surgery. APMIS, 115: 1001-1007. doi:10.1111/j.1600-0463.2007.00832.x

¹² Birgand G, Toupet G, Rukly S et al. Air contamination for predicting wound contamination in clean surgery: A large multicenter study. Am J Inf Control 43 (2015) 516-21

¹³ Brandt C., et al. Operating room ventilation with laminar airflow shows no protective effect on the surgical site infection rate in orthopedic and abdominal surgery. *Ann Surg.* 2008;248:695-700.

¹⁴ Maheshwari K. Room Ventilation Systems, chapter 9 in Operating Room Design Manual, American Society of Anesthesiologists 2012

 $^{^{15}}$ Avidan MS, Jones N, Ing R et al. Convection warmers – not just hot air. Anaesthesia 2997 (52) 1073-1076

¹⁶ McGovern PD, et al. Forced-air warming and ultra-clean ventilation do not mix. *J Bone Joint Surg Br.* 2011; 93-B:1537-44

 $^{^{17}}$ Memarzadeh F. Active warming systems to maintain perioperative normothermia in hip replacement surgery. *J Hosp Infect.* 2010; 1-2

¹⁸ Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection. http://www.msis-na.org/wp-content/themes/msis-temp/pdf/ism-periprosthetic-joint-information.pdf. Accessed 5/19/17

 $^{^{19}}$ Association of Perioperative Registered Nurses, "Perioperative Standards and Recommended Practices 2013"

²⁰ UPDATE: Mycobacterium chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T Heater-Cooler System: FDA Safety Communication https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm520191.htm. Accessed 5/19/17
²¹ http://safepatientwarming.com/spw/hosingreusecommingling/hosing/index.html. Accessed 5/19/17

CURRICULUM VITAE

ALEXANDER AUSTIN HANNENBERG, M.D.

81 Washburn Avenue, Wellesley, Massachusetts 02481 (781) 237-1930

E-mail: ahannenberg@partners.org

Born: Brooklyn, New York July 8, 1954

EDUCATION

Public Schools, City of New York A.B., Vassar College, Poughkeepsie, New York, 1975 M.D., Tufts University, Boston, Massachusetts, 1979

POSTGRADUATE TRAINING

Intern, Department of Medicine, St. Elizabeth's Hospital of Boston, 1979-1980

Resident, Department of Anesthesia, Beth Israel Hospital/Harvard Medical School, Boston, January, 1981 to December, 1982

Chief Resident, Department of Anesthesia, Beth Israel Hospital/Harvard Medical School, Boston, January-September, 1983

Fellow, Advanced Clinical Anesthesia, Department of Anesthesia, Beth Israel Hospital/Harvard Medical School, January - December 1983

Hospital Leadership Development Program, Harvard Business School, 2009

POSITIONS HELD

Chief Quality Officer (interim), American Society of Anesthesiologists, 2017-

Principal Consultant, ORDxRx Surgical Safety Solutions LLC, 2016-

Senior Research Scientist, Brigham & Women's Hospital (Ariadne Labs), 2014-

Associate Chairman, Department of Anesthesia, Newton-Wellesley Hospital, Newton, MA. 1991-2017 Medical Director, Henderson Day Surgery Center, Newton Wellesley Hospital, Newton, MA, 1991-1999 Tufts University School of Medicine, Department of Anesthesiology

Associate Clinical Professor, 1991-2006

Clinical Professor, 2006 –

Staff Anesthesiologist, Surgery Center of Waltham, MA., 1996 - 1998

Attending Anesthesiologist, Mount Auburn Hospital, Cambridge, MA., April, 1984-November 1990

Medical Director, Day Surgery Center, Mount Auburn Hospital, Cambridge, MA., August, 1984-1990

Attending Anesthesiologist, Youville Hospital, Cambridge, MA., April, 1984-1990

Attending Anesthesiologist, Beth Israel Hospital, Boston, MA., January-April, 1984

Clinical Instructor in Anesthesia, Harvard Medical School, January, 1984-June, 1991

Staff Physician, Emergency Department, Falmouth Hospital, July-December, 1980.

LICENSURE & CERTIFICATION

Diplomate, National Board of Medical Examiners, 1980

Massachusetts Board of Registration in Medicine License #46014

Diplomate, American Board of Anesthesiology, April, 1984, #11382

Recertification, American Board of Anesthesiology, May 1997; August 2006

Advanced Cardiac Life Support, 1980, 1997, 1999, 2001, 2003, 2006, 2008, 2011, 2012

Biomedical Research Investigators and Key Personnel Course, Collaborative Institutional Training Initiative, University of Miami, May 2015

Agency for Healthcare Research & Quality, TeamSTEPPS Master Trainer, August 2015

PROFESSIONAL ASSOCIATIONS

American Society of Anesthesiologists

President, 2010

President-Elect, 2009

First Vice President, 2008

Vice President for Professional Affairs, 2004-2008

House of Delegates, 1987-2011

Reference Committee Member: 1995, 1997, 1998, 1999, 2002

Board of Directors

Alternate Director (Massachusetts), October 1994-1997

Director (Massachusetts), October 1997-2003

Committee on Administrative Affairs, 1999-2003

Chair, 2002-2003

Administrative Council, 2004-2011

Committee on Economics, October 1994-2003

Chair, October 2001 -2003

Alternate Representative to AMA/Specialty Society Relative Value Update Committee, 1996

Representative to AMA/Specialty Society Relative Value Update Committee (RUC), 1997-2003

Task Force on Procedure Based Payment Systems, 1997-1998

Task Force on Strategic Planning, 1997-1998

Task Force on Data Management, 1998

Committee on Information Management, 1998-2000

Committee on Distinguished Service Award, 2006-2007; 2010-2012; 2016-2018

Chair, 2012

Chair, Committee on Annual Meeting Sites, 2008-2009

Committee on Surgical Anesthesia, 2009-

Judicial Council, 2012-2017

Chair, 2013

Chair, Steering Committee on Payment Reform 2015-

American Board of Anesthesiology

In-Training Examination Question Writer, 1997-2007

Oral Board Examiner, 2000-2015

Associate Examiner, 2004-2011

Senior Associate Examiner, 2011-2015

Joint Committee of ABA-ASA-AMA, 2006-2012

Massachusetts Society of Anesthesiologists

Executive Committee, 1984-

Chairman, Committee on Economics, 1988-

Representative to Medicare Carrier Advisory Committee 1993-

Secretary, 1987-1993

Vice President, 1993-1994

President-Elect, 1994-1995

President, 1995-1996

Nominating Committee, 1997-1999

Massachusetts Anesthesia Council on Education

Board of Directors, 1994-1996

Massachusetts Medical Society

Councilor, 1987-1989

Committee on Managed Care, 1993-2003

Interspecialty Committee, 1995-96

House of Delegates, 1996, 1998, 2001

Reference Committee "A" 1996

Committee on Professional Liability, 2003-2012

Vice-Chair, 2011-2012

Committee on Quality of Medical Practice

Advisor, 2016-

American Medical Association

Relative Value Update Committee (RUC) [alternate], 1996

Relative Value Update Committee (RUC), 1997-2003

Chair, Workgroup on Minimally Invasive Procedures, 1997

Practice Expense Subcommittee, 1997-1998

Administrative Subcommittee, 1998-2003

Chair, 1999-2001

Workgroup on Practice Expense Refinement, 1999

Conscious Sedation Workgroup, 2000-2003

Five Year Review of Work Values, Workgroup Chair, 2000

Five Year Review of Work Values, Facilitator, 2000

Physician Consortium for Performance Improvement

Perioperative Workgroup 2006

Chair, Anesthesia/Critical Care Workgroup 2006

Co-Chair, Anesthesia/Critical Care Workgroup, 2012

House of Delegates, Alternate Member, 2007-2010

New England Society of Anesthesiologists

Norfolk County (MA.) Medical Society

International Anesthesia Research Society

Medical Group Management Association

Anesthesia Administration Assembly

National Youth Leadership Forum on Medicine, Faculty 1993-2014

Massachusetts Peer Review Organization, Inc. (MassPRO)

Board of Directors, 2001-2008

Clerk, 2007-2008

Chair, Audit & Compliance Committee, 2007-2008

Foundation for Anesthesia Education & Research (FAER)

Board of Directors, 2002-2014

Chair, Medical Student Research Fellowship Committee 2003-2009; 2011-2012

Finance Committee, 2007-2012

Anesthesia Patient Safety Foundation (APSF)

Board of Directors, 2004-2013

World Federation of Societies of Anesthesiologists

U.S. Delegate, General Assembly 2008, 2012

American College of Surgeons

Surgical Quality Alliance, 2005-2009

Council on Surgical & Perioperative Safety, Board of Directors, 2008-

Secretary, 2011 Vice-Chair, 2012 Chair, 2013

Academy of Anesthesiology, elected 2009

Anesthesia Quality Institute

Board of Directors, 2010-2017 Vice Chair, 2012-2014 Treasurer, 2014-2017

ASA Charitable Foundation

Board of Directors, 2011-

President 2011-

Lifebox Foundation, Inc. (USA)

Board of Directors (Secretary), 2013-

Institute for Healthcare Improvement, Cambridge MA

Faculty, 2013 –

Emergency Manual Implementation Collaborative

Steering Committee 2013 –

European Society of Anesthesiology

Associate Member, 2014-

HOSPITAL/HEALTH SYSTEM ACTIVITIES

Board of Trustees, Newton-Wellesley Health System, July 2016-

Committee on Ethics, Newton-Wellesley Hospital, 2006-2009

Chair, By Laws Committee, Newton-Wellesley Hospital Medical Staff, 2001-2014

Strategic Leadership Group, Newton-Wellesley Hospital, 2014-2016

Joint Trustee-Staff Committee, Newton-Wellesley Hospital, 1999-2001

President, Newton-Wellesley Hospital Medical Staff, 2000

President-Elect, Newton-Wellesley Hospital Medical Staff, 1999

Secretary, Newton-Wellesley Hospital Medical Staff, 1997-1999

Executive Committee of the Medical Staff, Newton-Wellesley Hospital, 1999-2000 Chair, 2000

Partners Health System Contracts Committee, 1999-2001

Partners Health System Information Systems Steering Committee, 1999-2004

Partners Community Healthcare Inc. Managed Care Contracts Committee, 2005-2010

Partners Health System Medication Decision Support Steering Committee, 2004-2006

Partners Perioperative Executive Committee, 2013-2017

Newton Wellesley Physician Hospital Organization

Contracts Committee, Chair, 1999-2008

Board of Directors, 2005-2017

Chair, 2005-2014

Chair, Medical Records Committee, Newton-Wellesley Hospital, 1995-1999

Chair, Information Services Advisory Committee, 1996 – 2006

NeWell Physicians, Inc. [IPA] Board of Directors, 1996-1999

Operating Room Management Committee, Newton-Wellesley Hospital, January 1991-

Quality & Performance Improvement Committee, Newton-Wellesley Hospital, 1992-2001

Co-Chair, 1998-1999

Special Care Units Committee, Newton-Wellesley Hospital, 1991-1995

OTHER ACTIVITIES

Alumnae & Alumni of Vassar College

Nominating Committee, 1990-1993

Class of 1975 Vice President, 2000-2005

Vassar Club of Boston

Admissions Interviewer, 1976-

Scraggy Neck Recreation Association, Cataumet MA

Administrative Council, 1997-1998

Board of Governors, 2005-2010

President, 2008-2009

Commonwealth of Massachusetts Medical Malpractice Tribunal Member, 1994-

Plymouth Superior Court

Suffolk Superior Court

Middlesex Superior Court

Worcester Superior Court

Bristol Superior Court

Founder/Coordinator, Boston Marathon Runner's Injury Clinic, 2001-

Reviewer:

Journal of Clinical Anesthesia 2002

Anesthesia & Analgesia 2004, 2011, 2012, 2013, 2015

Health Affairs 2012

Anesthesiology 2013, 2015

Annals of Surgery, 2014

Neurosurgery, 2016

West Point Parents Club of Massachusetts, 2003-2010

Juror, Blue Cross-Blue Shield Association "Best of Blue National Awards Program in Medical & Pharmacy Management," 2005

Medically Induced Trauma Support Service, 2012 Leadership Committee

HONORS & AWARDS

Partners Health System, "Partners in Excellence" Award (individual), December 1999

Newton Wellesley Hospital, Board of Overseers, May 2001-

Overseer for Life, 2012-

"Generations of Leadership" Award, Newton-Wellesley Hospital, June 2001

Partners Health System, "Partners in Excellence" Award (team), December 2009

Partners Health System, "Partners in Excellence" Award (team), November 2011

Association of Anaesthetists of Great Britain & Ireland, Honorary Member (elected 2013)

Newton-Wellesley Hospital Patient Safety Award, March 2015

Distinguished Service Award (2015), American Society of Anesthesiologists

INVITED PRESENTATIONS

"Regional Anesthesia of the Airway", Massachusetts Anesthesia Council on Education Anesthesiology Update Course, Bermuda, 11/3/91

"Massachusetts Medicine: Beirut or Shangri La?," Massachusetts Anesthesia Council on Education Anesthesiology Update Course, Bermuda, 11/4/91

- "Anesthesia Reimbursement Policy Update," Massachusetts Anesthesia Council on Education Anesthesiology Update Course, Bermuda, 11/5/91
- "Basics of Anesthesia Economics", Massachusetts Society of Anesthesiologists Resident Section Symposium, 11/14/92
- "Basics of an Anesthesia Agreement", Massachusetts Society of Anesthesiologists Symposium on Managed Care Contracting in Anesthesia, 3/13/93
- "The Changing Business of Anesthesia", Children's Hospital-Boston/Harvard Medical School, Dept. of Anesthesia Grand Rounds, 6/30/93
- "The Economics of Private Practice", Massachusetts Society of Anesthesiologists Resident Section Symposium, 11/13/93
- "Current Economic Issues in Anesthesiology", Beth Israel Hospital (Boston)/Harvard Medical School, Dept. of Anesthesia Conference, 12/16/93
- "What I'm Really Doing About Managed Care", American Society of Anesthesiologists Annual Meeting, San Francisco, 10/18/94
- "Ins and Outs of Anesthesia Reimbursement", Massachusetts Society of Anesthesiologists Resident Section Symposium, 11/18/94
- "The Changing Business of Anesthesia", Beth Israel Hospital (Boston)/Harvard Medical School, Anesthesia Grand Rounds, 3/15/95
- "The Perils of RBRVS Payment in Anesthesia", Annual Meeting, Massachusetts Society of Anesthesiologists, 5/6/95
- "The Perils of Medicare RBRVS", MACE Winter Symposium, Stratton, VT, 1/27/96
- "Anesthesia and Medicare", Grand Rounds, Dept. of Anesthesia, Tufts-N.E. Medical Center, Boston, 2/5/96
- "New Topics in Airway Management," Annual Meeting, Massachusetts Society of PeriAnesthesia Nurses, Hyannis MA, 4/5/97
- "Basics of Anesthesia Reimbursement," Massachusetts Society of Anesthesiologists Resident Section Symposium, 5/4/97
- "Emerging Trends in Reimbursement: How it Affects the Operating Room," Southern New England Anesthesia Conference, Newport RI, 5/31/97
- "Managed Care Issues in Anesthesia," 17th Annual Anesthesiology Update, Colby College, Waterville ME, July 30, 1997
- "Medicare Anesthesia Issues Update," 17th Annual Anesthesiology Update, Colby College, Waterville ME, July 31, 1997
- "Analyzing the Profitability of Anesthesia Fee Schedules," ASA Conference on Practice Management, San Antonio TX, February 21, 1998
- "New Trends in Anesthesia Reimbursement," Medical Group Management Assn. Anesthesia Administration Assembly, Denver CO, May 4, 1998
- "Favorite Stories from the Federal Register: Government Regulation & Your Practice," Maine Society of Anesthesiologists Annual Meeting, September 12, 1998
- "Locating and Assessing a Practice Opportunity," Resident Conference, Beth Israel Deaconess Medical Center/Harvard Medical School Department of Anesthesia, Boston MA October 8, 1998
- "Medicare & Commercial Anesthesia Reimbursement," ASA Conference on Practice Management, San Francisco CA, February 21, 1999
- "Making the Transition from Residency to Practice," Mass. Society of Anesthesiologists Resident Component Seminar, Newton, MA, April 10, 1999
- "Anesthesia Compliance & Documentation," Berkshire Medical Center, Department of Anesthesia, Pittsfield MA, July 12, 1999
- "Anesthesiologist's Survival Guide to Contracting [panel]," American Society of Anesthesiologists Annual Meeting, Dallas TX, October 11, 1999

- "Pain Management Y2K," Mass. Society of Anesthesiologists Practice Management Seminar, Newton MA, December 4, 1999
- "Commercial Payments Based on the Medicare Fee Schedule," American Society of Anesthesiologists Practice Management Conference, Tampa FL, February 12, 2000
- "Introduction to Anesthesia Economics," Mass. Society of Anesthesiologists Resident Component Seminar, Boston MA, February 26, 2000
- "Medicare & Anesthesia Relative Values," Kentucky Society of Anesthesiologists Annual Meeting, Covington, KY, March 25, 2000
- "Favorite Stories from the Federal Register," Kentucky Society of Anesthesiologists Annual Meeting, Covington, KY, March 25, 2000
- "Economic & Regulatory Challenges in Anesthesia Practice," Grand Rounds, Department of Anesthesia/Critical Care, Beth Israel Deaconess Medical Center, Boston MA, January 10, 2001
- "ASA and the Medicare Fee Schedule," National Legislative Conference, American Society of Anesthesiologists, Washington DC, May 1, 2001
- "HCFA Building Blocks," Medical Group Management Association Anesthesia Assembly, Phoenix AZ, May 22, 2001
- "Malignant Hyperthermia Update," Newton Wellesley Hospital Surgical Services Conference, Newton MA, July 25, 2001
- "Economic & Regulatory Challenges In Anesthesia Practice," Grand Rounds, Department of Anesthesia, Tufts-New England Medical Center, Boston MA, August 20, 2001
- "Introduction to Anesthesia Economics," Anesthesia Grand Rounds, Brigham & Women's Hospital, Boston MA, August 29, 2001
- "ASA & the Medicare Fee Schedule 2002 Update," Practice Management Conference, American Society of Anesthesiologists, Phoenix AZ, February 2, 2002
- "Advances In Airway Management," Newton Wellesley Hospital Surgical Services Conference, Newton, MA, February 13, 2002
- "The Medicare Update Debacle of 2002," National Legislative Conference, American Society of Anesthesiologists, Washington DC, April 30, 2002
- "Introduction to Anesthesia Economics," Resident Seminar, University of Massachusetts Medical Center Department of Anesthesia, May 14, 2002
- "Medicare Update," Grand Rounds, University of Massachusetts Medical Center Department of Anesthesia, May 15, 2002
- "Update on Anesthesiology Reimbursement," MGMA Anesthesia Administration Assembly, Memphis TN, May 20, 2002
- "Anesthesia Economics Update," Grand Rounds, Department of Anesthesia, Baystate Medical Center, Springfield, MA., September 12, 2002
- "Anesthesia Practice Economics," Grand Rounds, Department of Anesthesia, Maine Medical Center, Portland, ME, September 19, 2002
- "Update on Anesthesia Economics," Annual Meeting, Ohio Society of Anesthesiologists/Cleveland Clinic Foundation, Cleveland OH, September 22, 2002
- "Payment Problems In Academic Anesthesia", Society of Academic Anesthesia Chairs/Association of Anesthesia Program Directors Annual Meeting, San Francisco, CA, November 8, 2002
- Program Director, 2002 Practice Management Seminar, Massachusetts Society of Anesthesiologists, Burlington MA, November 16, 2002
- "Medicare and Anesthesiology: Will It Ever Get Better?" 56th New York Postgraduate Assembly in Anesthesiology, New York, NY, December 8, 2002
- "What's Wrong with Medicare?" Anesthesia Grand Rounds, Boston University Medical Center, Boston MA January 13, 2003

- "The Federal Government and Anesthesia Practice" Anesthesia Grand Rounds, St. Elizabeth's Medical Center, Boston MA January 16, 2003
- "Medicare Forecast 2004," National Legislative Conference, American Society of Anesthesiologists, Washington DC, May 6, 2003
- "Anesthesiology Reimbursement Update," MGMA Anesthesia Administration Assembly, Montreal, QE, Canada, May 19, 2003
- "Payment for MAC and Conscious Sedation," Anesthesia Grand Rounds, Beth Israel Deaconess Medical Center, Boston MA, October 8, 2003
- "Coding and Compliance Considerations in Monitored Anesthesia Care," Society for Ambulatory Anesthesia Mid-Year Conference, San Francisco CA, October 10, 2003
- "Professional Fees and Other Departmental Financial Support Past, Present, Future," Society of Academic Anesthesiology Chairs/Association of Anesthesiology Program Directors Annual Meeting, Washington DC, November 7, 2003
- "Anesthesia Economics Update 2004", Minnesota Society of Anesthesiologists Fall Conference, Minneapolis MN, November 8, 2003
- "Future of Payment for MAC & Sedation" Minnesota Society of Anesthesiologists Fall Conference, Minneapolis MN, November 8, 2003
- "Future of Payment for MAC & Sedation" American Society of Anesthesiologists Practice Management Conference, Ft Lauderdale FL, February 8, 2004
- "The Ongoing Medicare Crisis," National Legislative Conference, American Society of Anesthesiologists, Washington DC, May 4, 2004
- "The Ongoing Medicare Crisis," Medical Group Management Association Anesthesia Administration Assembly, San Francisco CA, May 26, 2004
- "99 Years and Going Strong: ASA in 2004", New England Society of Anesthesiologists Annual Meeting, Scarborough ME, September 9, 2004
- "Payment Issues in Pain Management" Tufts University Master's Program in Pain Research, Education & Policy, Boston MA, October 6, 2004
- "Medicare Policy Update" Society of Academic Anesthesia Chairs Annual Meeting, Boston MA, November 5 2004
- "Minding Your Business: Payment Issues for the Decade," Grand Rounds, University of Massachusetts Medical School Department of Anesthesia, Worcester MA, November 17, 2004
- "Regulatory Triumphs and Disappointments," ASA Practice Management Conference, San Francisco CA, February 5, 2005
- "Coming In From The Cold," Maine Society of Anesthesiologists, Carrabasset Valley, ME, February 12, 2005
- "The Future of Anesthesiology Reimbursement," Rhode Island Society of Anesthesiologists, Cranston RI, April 6, 2005
- "The Future of Payment for Anesthesiology Services," Medical Group Management Association Anesthesia Administration Assembly Annual Conference, Colorado Springs CO, April 12, 2005
- "Pay for Performance in Anesthesiology," National Legislative Conference, American Society of Anesthesiologists, Washington DC, May 3, 2005
- "The Hospital Stipend Goldrush," Harvard Medical School Anesthesia Review & Update, Boston MA, May 17, 2005
- "100 Years & Going Strong: ASA in 2005," Oregon Society of Anesthesiologists Annual Meeting, Gleneden Beach OR, May 21, 2005
- "Legislation, Regulation & Interpretation," Oregon Society of Anesthesiologists Annual Meeting, Gleneden Beach OR, May 21, 2005
- "100 Years & Going Strong: ASA in 2005," Quad State Anesthesiologists Conference, Orange Beach AL, August 6, 2005

- "Perioperative Temperature Management," Newton Wellesley Hospital Perioperative Services Division, Newton MA, August 31, 2005
- "Pay for Performance in Anesthesiology," New England Society of Anesthesiologists Annual Meeting, Bretton Woods NH, September 9, 2005
- "The Hospital Stipend Goldrush," New England Society of Anesthesiologists Annual Meeting, Bretton Woods NH, September 10, 2005
- "Pay for Performance in Anesthesiology," Connecticut State Society of Anesthesiologists Annual Meeting, Westbrook CT, September 17, 2005
- "Overview Pay for Performance," American Society of Anesthesiologists Annual Meeting, Atlanta GA, October 24, 2005
- "Pay for Performance in Anesthesiology," Anesthesia Grand Rounds, Massachusetts General Hospital, Boston MA, December 8, 2005
- "Current Issues Forum," N.Y. State Society of Anesthesiologists Postgraduate Assembly, New York NY, December 11, 2005
- "Malignant Hyperthermia," Newton-Wellesley Hospital Surgical Services Conference, Newton MA, December 14, 2005
- "Pay for Performance: What It Means for Anesthesiology," New Jersey State Society of Anesthesiologists Annual Meeting, Monroe, NJ, March 25, 2006
- "Payment Issues Update," Medical Group Management Association Anesthesia Assembly, Tampa FL, March 29, 2006
- "Medicare 2007 Issues Review," National Legislative Conference, American Society of Anesthesiologists, Washington, DC, May 2, 2006
- "What Ails Medicare?" Anesthesiology Grand Rounds, George Washington University Medical Center, Washington, DC, May 3, 2006
- "The Practice of Anesthesiology: Where Are We Headed?" Keynote Harvard Medical School Department of Anesthesia & Critical Care "Update Your Skills," Brewster, MA, July 29, 2006
- "Panel: Pay for Performance in Anesthesiology" Annual Meeting, North Carolina Society of Anesthesiologists, Myrtle Beach SC, September 30, 2006
- "P4P: The View from the American Society of Anesthesiologists" Atlantic Health Systems
 Anesthesia/Surgery Pay for Performance-Health IT Symposium, Basking Ridge NJ, October 7,
 2006
- "Pay for Performance in Perioperative Care (panel)" American Society of Anesthesiologists Annual Meeting, Chicago IL, October 17, 2006
- "The Next Perfect Storm," Society of Academic Anesthesia Chairs Annual Meeting, Seattle WA, October 27, 2006
- "Science, Politics, Press and Money," Arkansas Society of Anesthesiologists Annual Meeting, Little Rock AR, October 28, 2006
- "P4P: At The Table or On The Menu," 60th Postgraduate Assembly in Anesthesia, New York, NY, December 10, 2006
- "P4P: Making it Work in Anesthesiology." 60th Postgraduate Assembly in Anesthesia, New York, NY, December 11, 2006
- "Are Our Services Necessary?" Conference on Practice Management, American Society of Anesthesiologists, Phoenix AZ, January 27, 2007
- "Federal Affairs and Your Practice," University of Chicago Anesthesia Billing & Management Seminar 2007, Las Vegas NV, March 25, 2007
- "Science, Politics, Press and Money ASA Update," Washington State Society of Anesthesiologists Annual Meeting, Seattle WA, March 30, 2007
- "Strategies for Keeping Academics in Academic Anesthesiology (panel)," Association of University Anesthesiologists, Chicago IL, April 27, 2007

- "Pay for Performance and the Anesthesiologist," Minnesota Society of Anesthesiologists Spring Conference, Minneapolis MN, April 28, 2007
- "The Hospital Stipend Goldrush," Minnesota Society of Anesthesiologists Spring Conference, Minneapolis MN, April 28, 2007
- "The Future of Anesthesia Practice: Where Are We Headed?," Medical Group Management Assn. Anesthesia Administration Assembly Annual Meeting, Seattle WA, May 2, 2007
- "Pay for Performance: The Law of the Land," American Society of Anesthesiologists Annual Legislative Conference, Washington DC, May 8, 2007
- "Quality Incentives and the Anesthesiologist," Texas Society of Anesthesiologists, Austin TX, September 8, 2007
- "Quality Incentives and the Anesthesiologist," Colorado Society of Anesthesiologists, Denver CO, September 9, 2007
- "Negotiating with a 500 lb Gorilla (workshop)," Colorado Society of Anesthesiologists, Denver CO, September 9, 2007
- "Medicare Reform, Quality and Pay for Performance," Accelerating Your Practice into the 21st Century R.I. & CT Societies of Anesthesiologists/ Brown University, Newport RI, September 15, 2007
- "The U.S. Experience with Non-Physician Anesthetists," Ontario Anesthesia Meeting, Niagara Falls, ON., September 28, 2007
- "What are the Economic and Political Drivers Behind P4P?" (panel), Annual Meeting, American Society of Anesthesiologists, San Francisco CA, October 15, 2007
- "Normothermia and the Center for Medicare and Medicaid Services Pay-for-Performance Initiative" in "Prevention of Surgical Wound Infections (panel)", Annual Meeting, American Society of Anesthesiologists, San Francisco CA, October 16, 2007
- "Threats to our Prosperity," Society of Academic Anesthesiology Chairs Annual Meeting, Washington DC, November 2, 2007
- "Pay-for-Performance and the Anesthesiologist," Midwest Anesthesia Conference, Illinois Society of Anesthesiologists, Chicago IL, November 3, 2007
- "Practice Management: P4P and Other Things You Need to Know," (panel), N.Y. Postgraduate Assembly in Anesthesia, New York, NY, December 9, 2007
- "Progress Report: Quality Incentives in Anesthesiology," ASA Conference on Practice Management, Tampa, FL, January 26, 2008
- "Quality Incentives and Anesthesiology," Academy of Anesthesiology, Desert Springs, CA, February 15, 2008 "Payment Issues Update," Grand Rounds, University of Massachusetts Medical School Department of Anesthesiology, Worcester MA, March 26, 2008
- "Pay for Performance," 4th Annual Ellison Pierce Symposium, Boston University School of Medicine, Boston MA, May 3, 2008
- "Economic Challenges in Anesthesia Practice," Harvard Medical School Anesthesia Review & Update, Boston, MA, May 16, 2008
- "The New Age of Anesthesiology," Medical Group Management Association Anesthesia Administration Assembly Annual Meeting, Philadelphia PA, May 19, 2008
- "Avoiding Performance Anxiety (panel)" ASA Annual Meeting, Orlando, FL, October 18, 2008
- "Economics, Politics, Payers and the ASA: Fight or Surrender? (panel), ASA Annual Meeting, Orlando FL, October 20, 2008
- "Perioperative Patient Registries: What ASA Members Need to Know and Why (panel), ASA Annual Meeting, Orlando FL, October 20, 2008
- "Practice Management: Quality and Safety," (panel), New York Postgraduate Assembly in Anesthesiology, New York, NY, December 14, 2008
- "ASA and Clinical Registries," ASA Practice Management Conference, Phoenix AZ, January 24, 2009

- "From Residency to Practice," Department of Anesthesiology, University of Virginia School of Medicine, Charlottesville VA, January 26, 2009
- "Organized Medicine and Professionalism," Department of Anesthesiology, Medical College of Virginia, Richmond, VA, January 27, 2009
- "ASA: Your Best Investment," Arizona Society of Anesthesiologists Annual Scientific Meeting, Scottsdale AZ, February 14, 2009
- "Performance Measurement in Anesthesiology," University of Chicago Anesthesia Business Seminar, Las Vegas NV, March 14, 2009
- "ASA: Achieving Excellence, Providing Value," National Medical Association Anesthesiology Section, Las Vegas NV, July 29, 2009
- "Health Care Reform and Anesthesiology," Department of Anesthesiology/Critical Care, Beth Israel Deaconess Hospital, Boston MA, November 25, 2009
- "Anesthesiology's Challenges & Opportunities," Keynote presentation, New England Anesthesia Research Conference, Boston MA, April 3, 2010
- "ASA: Indispensable to the Profession," Association of University Anesthesiologists 57th Annual Meeting, Denver CO, April 10, 2010
- "ASA Update," Society for Ambulatory Anesthesia Annual Meeting, Baltimore MD, May 1, 2010
- "Safe Use of Propofol," American Society for Gastrointestinal Endoscopy, President's Plenary Session, Digestive Diseases Week, New Orleans LA, May 3, 2010
- "ASA Update," Society for Obstetrical Anesthesia & Perinatology Annual Meeting, San Antonio, TX., May 13, 2010
- "Provider Payment Reform and the Anesthesiologist," Harvard Medical School Anaesthesia Update, Boston, MA., May 18, 2010
- "Health Care Reform and Anesthesiology," Medical Group Management Assn. Anesthesia Administration Assembly Annual Meeting, San Antonio, TX, May 26, 2010
- "Health Care Reform: Unfinished Business," Combined Anesthesia-Surgery Grand Rounds, Boston University Medical Center, Boston MA, June 7, 2010
- "A Visit to the Sausage Factory: American Health System Reform," Annual Congress, Association of Anaesthetists of Great Britain & Ireland, Harrogate, U.K., September 23, 2010
- "Performance Measurement in Anesthesiology," Turkish Society of Anesthesiology & Intensive Care Annual Congress, Antalya, Turkey, October 28, 2010
- "Workforce Issues and Health Policy," Grand Rounds, Department of Anesthesiology, Tulane University School of Medicine, New Orleans LA, November 10, 2010
- "Advancing the Specialty, Securing the Future," Grand Rounds, Department of Anesthesia/Critical Care, Beth Israel Deaconess Medical Center, Boston MA, November 17, 2010
- "Workforce Issues and Health Policy," University of Utah 56th Anesthesiology Postgraduate Review Course, Park City, UT, February 13, 2011
- "Health Care Reform & The Anesthesiologist," University of Utah 56th Anesthesiology Postgraduate Review Course, Park City, UT, February 14, 2011
- "Clinical Registries in Anesthesiology," University of Utah 56th Anesthesiology Postgraduate Review Course, Park City, UT, February 15, 2011
- "Origins of Anesthesiology's Medicare Problem," University of Utah 56th Anesthesiology Postgraduate Review Course, Park City, UT, February 15, 2011
- "Health Reform: Fact and Fiction," Department of Anesthesiology, Tufts Medical Center, Boston, MA, March 7, 2011
- "How ASA Serves Its Members," Opening Session, 2011 Annual Meeting, Chinese Society of Anesthesiologists, Ji'Nan, Shandong Pr., PR China, September 16, 2011
- "Drug Shortages in Anesthesiology," Testimony before Massachusetts State Legislature Joint Committee on Public Health, Boston MA, February 13, 2012

- "Making Surgery Safer Around the World," Ellison Pierce Symposium, Boston University School of Medicine, Boston MA, May 5, 2012
- "Measuring Physician Performance," Harvard Anesthesia Update, Boston MA, May 15, 2012
- "Global Oximetry," Harvard Anesthesia Update, Boston MA, May 17, 2012
- "Drug Shortages," University of Vermont College of Medicine Anesthesiology Grand Rounds, Burlington VT, May 31, 2012
- "Measuring Physician Performance," Grand Rounds, Department of Anesthesiology, Brigham & Women's Hospital, Boston MA, June 6, 2012
- "Physician Workforce," Grand Rounds, Department of Anesthesiology, St. Elizabeth's Medical Center, Boston MA, September 27, 2012
- "Performance Measurement Why?" Harvard Anesthesia Update, Boston MA, May 8, 2013
- "Clinical Registries" Harvard Anesthesia Update, Boston MA, May 8, 2013
- "Crisis Checklists in Your Practice," American Association of Surgical Physician Assistants Annual Conference, Alexandria VA, October 5, 2013
- "Regulatory Aspects of Propofol Administration," International Society for Anesthetic Pharmacology, San Francisco CA, October 11, 2013
- "A Team Approach to Surgical Fires," Institute for Healthcare Improvement National Forum, Orlando FL, December 11, 2013
- "Improving Surgical Safety Globally" American Academy of Anesthesiologist Assistants Annual Conference, Hilton Head SC, April 13, 2014
- "Crisis Checklists in Your Practice" American Academy of Anesthesiologist Assistants Annual Conference, Hilton Head SC, April 13, 2014
- "Global Health and Technology" [panel], Operation Smile NEXT Conference, Norfolk VA, May 17, 2014
- "Cirugia Segura Salve Vidas," Junto Ejecutivo, Confederacion Latinoamericano de Sociedades de Anestesiologia, Punta Cana RD, May 29, 2014
- "Cognitive Aids to Improve Crisis Management," Institute for Healthcare Improvement National Forum, Orlando FL, December 10, 2014
- "Cognitive Aids to Improve Crisis Management," Grand Rounds, Beth Israel Deaconess Hospital, Department of Anesthesiology & Critical Care, Boston MA February 11, 2015
- "Cognitive Aids to Improve Crisis Management," Winchester Medical Center, Winchester VA, April 16, 2015
- "Emergency Manuals & Crisis Checklists Where Are We?" Harvard Anesthesia Review, Boston MA, May 12, 2015
- "Introducing the Use of Emergency Manuals as a Team Sport" Anesthesia Patient Safety Foundation Consensus Conference, Phoenix AZ, September 9, 2015
- "Projecto Lifebox en Latinoamerica," Congreso de la Confederacion Latinoamericano de Sociedades de Anesthesiolgia, Lima Peru, September 23, 2015
- "Implementing Emergency Checklists," American College of Surgeons Clinical Congress 2015, Chicago IL, October 6, 2015
- "Implementing Emergency Manuals: What's the Secret Sauce?" American Society of Anesthesiologists Annual Meeting, San Diego CA, October 27, 2015
- "Preventing Surgical Fires" Central American Otolaryngology Congress, Guatemala City, November 11, 2015
- "Crisis Checklists to Improve Critical Event Management," Central American Otolaryngology Congress, Guatemala City, November 11, 2015
- "Anesthetic Considerations in Head & Neck Cancer," Central American Otolaryngology Congress, Guatemala City, November 11, 2015
- "Anesthetic Care of the Patient with Obstructive Sleep Apnea," Central American Otolaryngology Congress, Guatemala City, November 12, 2015

- "Lifebox: The Next Five Years of Making Surgery Safer," Ariadne Labs, Harvard School of Public Health, Boston MA, May 12, 2016
- "MACRA: Current Status," American Society of Anesthesiologists Legislative Conference, Washington DC, May 17, 2016
- "Scaling Innovation to Local Contexts," Roadmap to 2030: Surgery's Essential Role in Achieving Health for All, The G4 Alliance, New York, NY, September 21, 2016
- "Cognitive Aids to Improve OR Crisis Management," Asian Perioperative Nurses Association Congress, Hong Kong, October 9, 2016
- "Crisis Checklists: Implementation Lessons Learned from the Field," Asian Perioperative Nurses Association Congress, Hong Kong, October 10, 2016
- "Cognitive Aids to Improve OR Crisis Management," Department of Anesthesiology, Queen Mary Hospital
 University of Hong Kong College of Medicine, Hong Kong, October 11, 2016
- "MACRA Total Transformation of Medicare Payment," American Society of Anesthesiologists Annual Meeting, Chicago IL, October 25, 2016
- "Crisis Checklists Don't Implement Themselves," Academy of Anesthesiology 2017 Meeting, Amelia Island, FL. March 25, 2017
- "Development & Implementation of L&D Crisis Checklists," Partners Healthcare Quality & Safety Symposium, Newton MA, March 31, 2017
- "Total Transformation of Medicare Payment," Harvard Anesthesia Update 2017, Boston, May 8, 2017
- "Cognitive Aids to Improve OR Crisis Management," Harvard Anesthesia Update 2017, Boston, May 8, 2017
- "MACRA's Second Birthday," ASA Legislative Conference, Washington DC, May 13, 2017
- "Practical Tips for Healthcare Checklist Design and Implementation," National Patient Safety Foundation Congress, Orlando FL, May 19, 2017

VISITING PROFESSORSHIPS & NAMED LECTURESHIPS

- Emanuel M. Papper Visiting Professor, University of Miami School of Medicine, Department of Anesthesiology, Miami FL, October 30-31, 2002
- Visiting Professor, Department of Anesthesiology, Mt. Sinai School of Medicine, New York NY, March 2-3, 2004
- The John Hedley-Whyte Annual Lecture, Department of Anesthesiology, Critical Care & Pain Medicine, Beth Israel Deaconess Medical Center/Harvard Medical School, September 13, 2005
- Ralph M. Waters MD Visiting Professor of Anesthesiology, University of Wisconsin Medical School, Madison WI, November 7-8, 2005
- Visiting Professor, Weill Medical College of Cornell University (New York Presbyterian Hospital), Department of Anesthesiology, New York NY, April 10, 2006
- Visiting Professor, Department of Anesthesiology, Baylor College of Medicine, Houston TX, September 26, 2007
- Nicholas G. DePiero Lecturer, Ohio Society of Anesthesiologists, Cleveland OH, September 13, 2008
- Visiting Professor, Department of Anesthesiology, Dartmouth-Hitchcock Medical Center, Lebanon NH, December 2-3, 2008
- William B. Jensen Memorial Lecture, Michigan Society of Anesthesiologists, Troy MI, February 28, 2009
- Visiting Professor, Department of Anesthesiology, Mayo College of Medicine, Rochester MN, October 5, 2010
- Professor Dr. Sadi Sun Annual Lecture, Turkish Society of Anesthesiology & Intensive Care, Antalya, Turkey, October 27, 2010

- Frederick Haugen, M.D. Memorial Lecture, Oregon Society of Anesthesiologists, Portland OR, December 5, 2010
- Visiting Professor, Department of Anesthesiology & Perioperative Medicine, Oregon Health & Science University, Portland OR, December 6, 2010
- Richard N. Terry, M.D. Graduation Speaker (Inaugural), University at Buffalo Department of Anesthesiology, June 18, 2011
- Visting Professor, Shanghai Jiaotong University, Ruijin Hospital, Shanghai, PR China., September 13, 2011 Richard Browning Memorial Lecture, Brown University Medical School, Providence RI, May 2, 2015
- W. Heinrich Wurm (Inaugural) Lecture, Tufts University School of Medicine Department of Anesthesiology & Perioperative Medicine, June 10, 2016
- Anesthesia Patient Safety Foundation-American Society of Anesthesiologists Ellison C. Pierce, Jr., M.D. Memorial Patient Safety Lecture, "Patient Safety Beyond Our Borders: Different but the Same", October 22, 2016

PUBLICATIONS

- Hannenberg, A. What three things does drink provoke? New Eng J Med 296:118, 1977 [letter]
- Beck, C.W., Greenlie, J., Diamond, M.P., Macchiarulo, A.M., Hannenberg, A.A., Hauck, M.S. The chemical identification of Baltic amber at the celtic oppidum Stare Hradisko in Moravia, J. Archaelogical Science 5:343, 1978
- Hannenberg, A.A. An atraumatic method for topical application of local anesthetics to the nasal mucosa. Anesthesiology 59:596-597, 1983 *[letter]*
- Hannenberg, A.A., MacArthur, J.D. Establishing a pain clinic *in* <u>Pain Management</u> (J.M. Stein, C.A. Warfield, eds.) International Anesthesia Clinics, v. 21, Little, Brown, Boston, 1983
- Hannenberg, A.A., Satwicz, P.R., Dienes, R.S., Jr., O'Brien, J.C. A device for applying CPAP to the nonventilated upper lung during one-lung ventilation. II. Anesthesiology 60:254-255, 1984 [letter]
- Courtiss, E.H., Goldwyn, R.M., Joffe, J.M., Hannenberg, A.A. Anesthetic Practices in Ambulatory Aesthetic Surgery. Plastic and Reconstructive Surgery 93:792, 1994.
- Hannenberg, A.A. A regional anesthetic technique for ankle arthroscopy. Regional Anesthesia 20:357-8, 1995 [letter]
- Hannenberg, A.A. Fixing the Medicare Fee Schedule. Anesthesia Awakenings 3:3, Medical Group Management Association, 1996
- Hershey, M.D., Hannenberg, A.A. Gastric distention and rupture from oxygen insufflation during fiberoptic intubation. Anesthesiology 85:1479, 1996
- Hannenberg, A.A. Anesthesia Preoperative Evaluation Clinic. Anesthesiology 86:259, 1997 [letter]
- Hannenberg, A.A. Analyzing the Profitability of Anesthesia Fee Schedules in <u>Practice Management: Only the Fit Survive</u>, American Society of Anesthesiologists, 1998
- Hannenberg, A.A. Relative Value Analysis Software [CD-ROM], American Society of Anesthesiologists, 1998
- Hannenberg, A.A. Medicare-based Commercial Reimbursement Rates How to Fight Back in <u>Practice Management: Anatomy of the Bargain</u>, American Society of Anesthesiologists, 1999
- Hannenberg, A.A. Commercial Payments Based on the Medicare Fee Schedule in <u>Practice Management</u>, American Society of Anesthesiologists, 2000
- Liang, B.A., Hannenberg, A.A, Johans, T.G. Negligence in Supervision: A Case of Failed Resuscitation. Journal of Clinical Anesthesia 13:44-48, 2001
- Hannenberg, A.A. "Contracting Challenges In Anesthesiology", Medical Group Management Update 40:10, p. 7, May 15, 2001
- Hannenberg, A.A. "Toward Fair and Reasonable Fees In Obstetrical Anesthesia," American Society of Anesthesiologists Newsletter, 65(12): 21. December 2001

- Hannenberg, A.A. "Private Payer Perils," American Society of Anesthesiologists Newsletter 66:5, p 24, May 2002
- Hannenberg, A.A., Scott, M. "Revisiting Medicare Fees for Resident Supervision," American Society of Anesthesiologists Newsletter 66(12): 13, December 2002
- Hannenberg, A.A. Payment for Procedural Sedation, Current Opinion in Anæsthesiology 17:171-176, 2004 Hannenberg, A.A. "Anesthesiology's Seat at the Table," American Society of Anesthesiologists Newsletter 68:6, p.2, June 2004
- Hannenberg, A.A., Cohen, N.A. "Intraservice Time is Not a Proxy for Operating Room Time" Anesthesiology 101:1041, 2004. [letter]
- Hannenberg, A.A. "Pay for Performance: More Opportunity than Threat," American Society of Anesthesiologists Newsletter 69(7): 4-5, July 2005
- Miller R.D., Hannenberg A.A. "Anesthesiology's Choices for the Next Century," ASA Newsletter Special Centennial Issue, pps.36-37, August 2005
- Hannenberg, A.A. "Mirror, Mirror on the Wall...," Administrative Update, American Society of Anesthesiologists Newsletter 70(7):3, July 2006
- Hannenberg, A.A. "Making Scientists Out of Students" American Society of Anesthesiologists Newsletter 70(10):8-9, October 2006
- Hannenberg, A.A., Merrill, D.G. "Pay for Performance in Pain Medicine," American Society of Anesthesiologists Newsletter, 70(12):15-17, December 2006
- Hannenberg, A.A. "Are Our Services 'Medically Necessary'?" Practice Management 2007, American Society of Anesthesiologists, Park Ridge, IL
- Hannenberg, A.A. "Clinical Patient Registries: Their Day Has Come" American Society of Anesthesiologists Newsletter, 71(7):3, July 2007
- Hannenberg, A.A. "Estimates of Cost Savings from Anesthetic Management" Canadian Journal of Ophthalmology 42:756, 2007 (letter)
- Hannenberg, A.A. "Research for the Common Good," American Society of Anesthesiologists Newsletter 72(4):3, April 2008
- Hannenberg, A.A., Sessler, D.I. "Improving Perioperative Temperature Management [editorial]" Anesthesia & Analgesia 107:1454, 2008
- Hannenberg, A.A. "Physician Shortage: The Rest of the Story" American Society of Anesthesiologists Newsletter, 73(2):6, February 2009
- Hannenberg, A.A. "Introduction: Financial Considerations" in Anesthesia Outside the Operating Room," Anesthesiology Clinics 2009; 27:5-6
- Hannenberg, A.A., Warner, M.A. "The Registry Imperative" (editorial), Anesthesiology 2009;111:687-9
- Hannenberg, A.A. "Finding Value in Volunteerism," American Society of Anesthesiologists Newsletter, 74(1):6, January 2010
- Hannenberg, A.A. "Conflicts of Interest in Expert-authored Practice Parameters, Standards, Guidelines, Recommendations," (*letter*) Anesthesiology 2010;113:752-3
- Cohen, N.A., Hannenberg, A.A. "Risk Stratification Index: An Important Advance in Comparing Health Care Apples to Oranges," (editorial). Anesthesiology 2010:113:1004-6
- Hannenberg, A.A. "Providers of Anesthesia: Does Quality Vary?" (letter) Health Affairs 2010; 29(10):1972
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UPDATE: Mycobacterium chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T Heater-Cooler System: FDA Safety Communication

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Dr. Wenzel Science Day Presentation, May 19, 2016

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Expert Report of William Jarvis

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September 6, 2017

Deborah Lewis, Esq. Blackwell Burke 431 South 7th Street, Suite 2500 Minneapolis, MN 55415

Dear Ms Lewis:

In my May 30th letter presenting my expert opinion on the safety of the Bair Hugger forced air warming device, I indicated that, as a clinical anesthesiologist, I placed a high value on the detailed and impartial reviews of the available evidence on this subject from a group of highly reputable organizations (page 2).

I have recently had the opportunity to review the "Letter to Health Care Providers – Information about the Use of Forced Air Thermal Regulating Systems" dated August 30, 2017 from the U.S. Food and Drug Administration. In this letter, the FDA states that these systems "have been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients" and goes on to say that the agency "continues to recommend" their use. The FDA reports that they collected analyzed data from a variety of sources and was "unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection."

Inasmuch as the FDA not only has no commercial interest in the topic, it has a statutory responsibility to regulate devices, protect patients from hazard and require effective warnings where appropriate. In this instance, the FDA is highlighting the specific risks of <u>omitting</u> the use of thermoregulation systems in surgical patients.

This information from the nation's authority on the safety of medical devices further underscores the validity of the conclusions I presented in my earlier letter and will be a part of my testimony at trial. I certify under penalty of perjury that the above statements in this supplemental expert report dated September 6, 2017 are true and correct. Executed on September 6, 2017.

Sincerely yours,

Alexander A. Hannenberg, M.D.

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